Patent Prosecution Challenges to Biotechnology Inventions

Ph.D. Synopsis

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INTRODUCTION

Patent plays an important role in fostering research and development in a country. It encourages innovation, which assures that the quality of human life is continuously enhanced[1]. Scientific and technological advances have created new waves of innovation, notably in biotechnology, more particularly in the field of *Omics*[2] inventions. The trend of protecting inventions based on DNA and protein sequences has dramatically increased around the world in the past few years. The complexity of patent applications related to DNA and protein technology are unimaginable which further leads to huge prosecution challenges (**Fig.1**). Assessing a biotechnology[3] invention is more challenging because of three main reasons. First, biotechnology is a field of applied biology and is involved biology and chemistry, however, in many instances it also dependents on the knowledge and method from outside the sphere of biology. Second, claims of biotechnology inventions are very complex in nature and which forces a judge or patent examiner to deal with very fundamental issues such as the significance of the term "human" in describing a protein. And third, it raises important policy questions[4]. DNA or peptide molecules can be treated as a chemical substance having their own sets of functionality and *as such* they qualify as a composition of matter with respect to general patentability criteria. However, challenges go far beyond this apparently simple definition when questions regarding obviousness and area of protection arise, especially, for basic research and development in the area of genomics and proteomics (**Type-II, Fig.1**). In view of the ever increasing challenges towards patenting modern biotechnological products or the processes directed to DNA and peptide molecules, various

[1] WIPO, Faq: "Patents provide incentives to individuals by offering them recognition for their creativity and material reward for their marketable inventions. These incentives encourage innovation**,** which assures that the quality of human life is continuously enhanced." < http://www.wipo.int/patentscope/en/patents_faq.html#patent >

[2] **"***Omics"* generally refers to a field of study in biology ending with *–omics*, like gen*omics* (study of genes and genomes), prote*omics* (study of proteins). The suffix *–ome* is widely used to address the objects of study of a particular field of biology, such as genome and proteome. Bio-informaticians and molecular biologists are believed to be amongst the first scientists to start to apply the "-ome" suffix widely. However, *Omics* also includes transcriptomics (study of mRNA), metabolomics (study of metabolites) and pharmacogenomics (a highly specialized branch of pharmacology which deals with the study of impact of genetic variation on drug response in patients by correlating gene expressions and single nucleotide polymorphisms (SNPs) with a drug's efficacy or toxicity. However, in the present synopsis only genomics (DNA related technology) and proteomics (protein or peptide related technology) have been considered as *Omics*.

[3] In many instances biotechnology is also dependent on the knowledge and method of nano-technology, chemical engineering, information technology, bio-robotics etc.

[4] *Kevin J. MacGough and Daniel P. Burke*, Harvard Journal of Law & Technology, Vol.6, Pg.86.

countries have forced to set up various statutory requirements and guidelines with the common objective of promoting research and development in the country by maintaining a maximum possible harmonization between their patent practices and ultimately to comply with TRIPS obligations.

SCOPE OF THE RESEARCH

The present academic research is aimed at the study of challenges in patenting innovations in the field of proteomics and genomics around the world. It further identifies and analyzes the issues related to inventive step and broad claiming system of patent applications directed to DNA and protein homology, structural bio-informatics products, ESTs etc. The present research conducts a comparative study regarding patentability of biotech inventions in various jurisdictions and observes the harmonization of patent practices between them which finally ends up with concluding India's position. It further analyzes the jurisprudence of Indian patent practice and generates suggestions which might be helpful for the policy maker to formulate a balanced and justified guidelines towards patenting biotechnology inventions.

LITERATURE REVIEW

A number of literatures and references have been collected and studied. The list may include, however not limited to the following.

- Nikolaus Thumm, Swiss Federal Institute of Intellectual Property, *Research and Patenting in Biotechnology*. < **http://www.ige.ch/E/jurinfo/j100.htm#2 >**

The report of Nikolaus Thumm presents the results of a survey with the Swiss biotechnology industry, conducted by the Swiss Federal Institute of Intellectual Property in 2003. The survey was a consequence of the Swiss Federal Council's decision, on December 7, 2001, to hold a public consultation regarding the preliminary draft of the partial revision of the Swiss patent law.

- Kima Uche, Biochemistry 118Q: Genomics & Medicine, *Genomics & Patents: Human Heritage and the Cost of Innovation*.

Kima Uche attempted to illuminate some of the bioethical dilemmas surrounding genetic patents and offered some insight on solutions proposed by notable figures and on bioethical dilemmas.

- Mircea Achiriloaie *et.al*, originally published in the Suffolk University Law School Journal of High Technology Law. The authors through some lights on the necessity of critical IP Laws with regard to patenting modern biotechnology inventions.
- Report of the Secretary's Advisory Committee on Genetics, Health and Society; *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, < http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf>

The report provided some advice on the broad range of policy issues raised by the development and use of genetic technologies as well as their charge to examine the impact of gene patents and licensing practices on access to genetic testing.

- HUGO Intellectual property committee statement on patenting of DNA sequences < http://www.hugo-international.org/img/ip_dna_2000.pdf>

This report is based on the study of patenting development in the area of genomics and has analyzed its possible impact specifically on the future of genomic research.

RESEARCH OBJECTIVES

- To analyze the policy factors that foster patenting of biotechnology inventions in India
- To examine the scope of patenting biotechnology inventions in India in the post-product patent regime
- To compare the norms related to prosecution of biotechnology inventions across jurisdictions
- To formulate a guideline that will help in patenting biotechnology inventions in India

RESEARCH HYPOTHESIS

Even after completion of several years as a TRIPS signatory country, Indian patent practice is still not well settled with regard to patenting of biotech inventions. No significant approach has been taken by the Indian Patent Office which is able to address the doubts of patenting biotech inventions in India. It is likely that lack of proper guidelines creates a great confusion. It excludes some patents that should be granted and fails to exclude others that should not.

Interpretation of patentable subject matter jurisprudence with regard to biotechnology inventions is difficult without a logical and justified alternative. Therefore, a balanced supplementary material is desirable which is helpful in interpreting the statutory requirements for patenting biotechnology inventions in India. The present research work addresses this requirement and directed to formulate policy and principles which can serve as a guideline in patenting biotechnology inventions in India.

RESEARCH QUESTIONS

1. What is the present position of the Indian Patents law with regard to patenting biotech inventions, e.g., DNA sequences, ESTs, structural bio-informatics products, SNPs, homologous DNA and proteins, molecular screening methods etc?

2. What is the current position in USA, Europe and Japan (major patent offices) with regard to patenting biotechnology (*proteomics-genomics*) inventions?

3. What are the commonalities and distinctions between India and other jurisdictions with regard to patenting biotech inventions?

4. What is the scope of legal protection of biotech products e.g. isolated DNA, peptides, and homologous sequences as reflected in patent claims?

5. Whether the Structural bioinformatics products e.g. atomic models of novel proteins (which have tremendous importance in drug discovery) are patentable under the prevailing Indian Patents Act?

6. Whether a supplementary material can be formulated so that statutory requirements of the Indian patents Law with regard to patenting biotechnology can be interpreted in a more logical and justified manner?

RESEARCH METHODOLOGY

The present academic research work is *techno-legal* in nature which involves analysis of various national and international laws/arrangements with regard to statutory requirements of patenting biotech inventions (mainly *proteomic-genomic* products and process), leading court judgments in this area, policies etc. During the interpretation of statutory requirements, the present research work will also carry out *techno-legal* study of Office Actions of the Examiners, decision/directions of various patent granting authorities and conduct a comparative analysis which will ultimately reveal the trend of harmonization between patent practices (e.g. USPTO, EPO, JPO etc) in the area of biotechnology. These documents will be freely available in the internet[5] however; specific information/documents etc. can also be procured from the patent office and other offices, if and when required. In this connection, views of the examiners, researchers[6] on a particular issue may also be taken, if required.

In the present *techno-legal* research, technical analysis of biotechnology information related to patents will be carried out with the help of various biotechnology information resources and patent-informatics tools[7]. It is an integral part of the present academic research to conduct in-depth analysis regarding the validity of the granted patents directed to DNA and protein sequences in order to measure the legal scope of protection with the help of various patent-informatics and bio-informatics tools[8]**.** Various policies, directives etc. will also be analyzed and if required, views of various institutes involved in these areas will also be taken.

TENTATIVE CHAPTERISATION

1. Introduction
2. Biotechnology(*omics*) Research and inventions and impact in the society
3. Complexity of Biotech patent applications
   3.1 Patentable subject matter jurisprudence

[5] Freely available data bases like USPTO patent database, USPTO Public PAIR, esp@cenet, WIPO patent database, Patent Scope (WIPO), Indian Patent Office database-IPAIRS, BigPatents.
[6] International Cancer Genome Consortium (ICGC)-National Institute of Biomedical Genomics (NIBMG), Kalyani, W.B. (India Chapter)
[7] National Center for Biotechnology Information (NCBI), European Bio-informatics Institute (EBI), ExPASy, PatTool
[8] Patent Lens, Basic Local Alignment Search Tools (BLAST)

3.2 Assessment of merit of the invention in view of inventive step and industrial application

3.3 Upstream research and reach-through claiming strategy in the area of proteomics and genomics patent applications

3.4 Scope of protection of claims for *omics* patent applications and cross-species patent coverage

4. Comparative study and analysis of patenting biotech inventions across jurisdictions and harmonization of patent practices
5. Indian patent Regime and current position

5.1 Subject matter jurisprudence-exceptions and exclusions

5.2 Assessment of merit of biotech patent applications, inventive step, industrial application

5.3 Identification of gaps in the Indian Patents (Amendment) Act,1970

5.3.1 Invalidity study of *omics* inventions-a special focus on GURT (Genetic Use Restriction Technology) patent applications

6. Formulation of guideline for patenting biotech inventions in India

6.1 Study and Analysis of Court judgments (India and other jurisdictions)

6.2 Study and Analysis of existing guidelines/directive/policies of various countries

7. Conclusion

BIBLIOGRAPHY

1. Nikolaus Thumm, *Research and Patenting in Biotechnology;* Swiss Federal Institute of Intellectual Property. < **http://www.ige.ch/E/jurinfo/j100.htm#2 >**
2. Kima Uche, *Genomics & Patents: Human Heritage and the Cost of Innovation;* Biochemistry 118Q: Genomics & Medicine
3. Report of the Secretary's Advisory Committee on Genetics, Health and Society; *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests*, < http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf>
4. HUGO Intellectual property committee statement on patenting of DNA sequences < http://www.hugo-international.org/img/ip_dna_2000.pdf>

5. S.Lall and Manuel Albaladejo; *Indicators of the Relative Importance of IPRs in Developing Countries;* International Centre for Trade and Sustainable Development International Environment House (ICTSD) and United Nations Conference on Trade and Development (UNCTAD) June 2003; ISSN 1681-8954
6. Shamnad Basheer; *"Policy Style" Reasoning at the Indian Patent Office;* Sweet & Maxwell Ltd and Contributors 2005
7. Kevin J. McGough and Daniel P. Burke, *A Case for Expansive Patent Protection of Biotechnology invention*; Harvard Journal of Law & Technology;Volume 6, 1992
8. Michael Risch; *Everything is patentable*; Villanova University School of Law 2008
9. Prof. Lionel Bently, Prof. Brad Sherman, Prof Denis Borges Barbosa, Prof. Shamnad Basheer, Prof. Coenraad Gold; WIPO Standing Committee on Law of Patents; *Exclusions from Patentability and Exceptions and Limitations to Patentees' Rights, WIPO*
10. MIT, *How does Intellectual Property Support the Creative process of Invention?*; The Lemelson-MIT program. < http://web.mit.edu/invent/n-pressreleases/downloads/ip.pdf>
11. Jorge L. Contreras, *Bermuda's Legacy: Policy, Patents and the Design of the Genome Commons;* Washington University in St.Louis, School of Law 2010. < http://ssrn.com/abstract=1667659>
12. Eileen M.Kane, *Splitting the Gene: DNA patents and the Genetic Code*; Tennessee Law Review 2004, Vol. 71:707.

" *Der Urquell aller technischen Errungenschaften ist die göttliche Neugier und der Spieltrieb des bastelnden und grübelnden Forschers und nicht minder die konstruktive Phantasie des technischen Erfinders* **" --- Albert Einstein[9], Technical Assistant Examiner, Swiss Patent Office**

" *The source of all technical achievements is the divine curiosity and playfulness of tinkering and brooding investigator and no less the constructive imagination of the inventor's technical* **"**

---Albert Einstein, Technical Assistant Examiner, Swiss Patent Office

[9] Albert Einstein was started his career in 1902 as a technical assistant examiner at the Swiss Patent Office. His famous statement at the number 2 Einsteinstrasse. < https://www.ige.ch/index.php?id=289&L=3 >

CHALLENGES IN PATENTING BIOTECHNOLOGY INVENTIONS

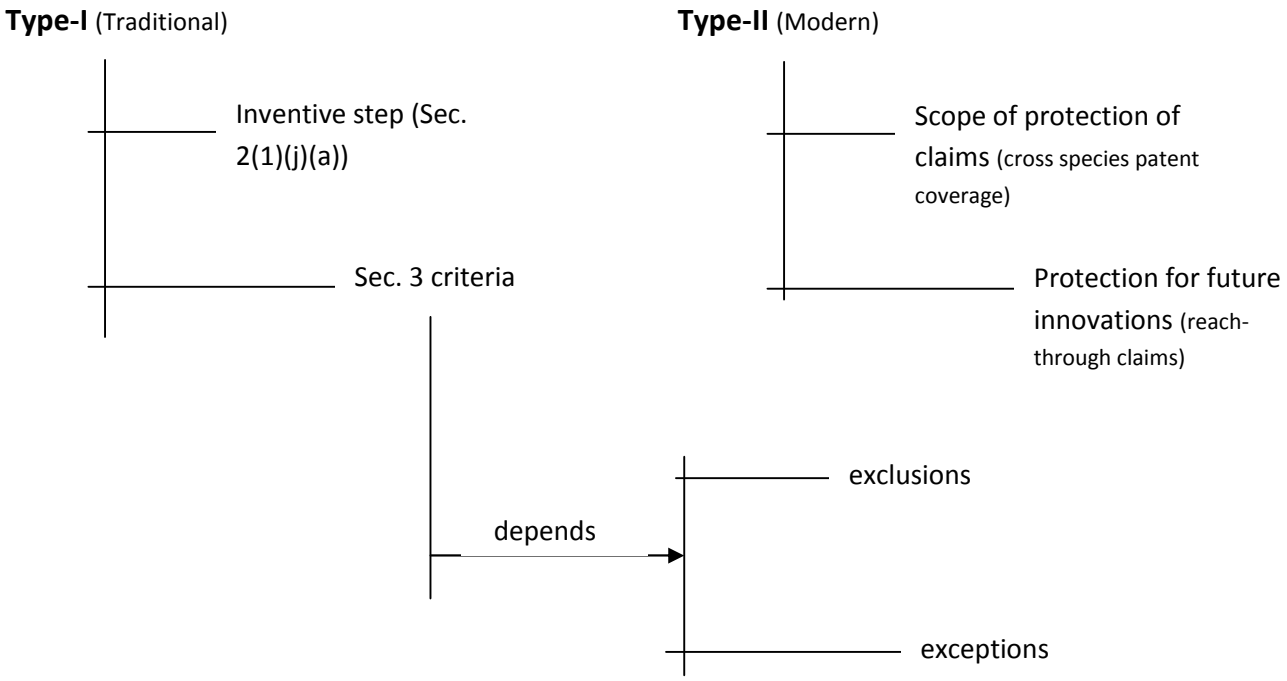

Fig.1